

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ALNYLAM PHARMACEUTICALS,  
INC.,

Plaintiff,

v.

MODERNA, INC., MODERNATX,  
INC., and MODERNA USA, INC.,

Defendants.

Civil Action No. 22-335-CFC  
(CONSOLIDATED)

**ALNYLAM PHARMACEUTICALS, INC.’S  
OPENING BRIEF IN SUPPORT OF ITS MOTION FOR LEAVE TO  
AMEND ITS COMPLAINT AGAINST  
MODERNA, INC., MODERNATX, INC., AND MODERNA USA, INC.**

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Dated: February 15, 2023

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Plaintiff Alnylam Pharmaceutical, Inc. (“Alnylam”) moves, under Rule 15 of the Federal Rules of Civil Procedure and within the time set under the Scheduling Order (D.I. 31), for leave to amend its Complaint to assert infringement of claims 1–7, 10-18 and 21–25 of U.S. Patent No. 11,590,229 (the “’229 Patent”) against Moderna, Inc., ModernaTX, Inc., and Moderna USA, Inc. (collectively, “Moderna” or “Defendants”). Clean and redlined copies of the proposed amended pleadings are attached as Exhibits 1-3, along with an infringement claim chart for the ’229 Patent at Exhibit 11.

## **I. NATURE AND STAGE OF THE PROCEEDINGS**

This is an action for patent infringement in which Alnylam alleges that Moderna’s COVID-19 vaccines infringe Alnylam’s patents. On March 17, 2022, Alnylam filed its Complaint against Moderna alleging infringement of U.S. Patent No. 11,246,933 (the “’933 Patent”). Moderna moved for partial dismissal on May 23, 2022. (D.I.11, D.I. 12.) On July 12, 2022, U.S. Patent No. 11,382,979 (the “’979 Patent”)<sup>1</sup> issued and Alnylam filed a second action against Moderna alleging infringement of the ’979 Patent. This Court issued a Stipulation and Order consolidating the two cases on July 27, 2022. (D.I. 25.)<sup>2</sup>

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<sup>1</sup> The ’933 Patent and ’979 Patent collectively are referred to as the “Asserted Patents.”

<sup>2</sup> The proposed amendment would result in a single complaint asserting the

On September 1, 2022, the Court held a Rule 16 conference, and then on September 13, 2022 entered a schedule through trial. (D.I. 31.) The deadline for this motion was set for February 15, 2023. (*Id.* at 30.) The Joint Claim Construction Brief is due on June 28, 2023. (*Id.*) A claim construction hearing is scheduled to take place August 9, 2023, and fact discovery closes on November 1, 2023. (*Id.*) Trial is scheduled to begin November 12, 2024. (*Id.* at 31.)

## **II. SUMMARY OF THE ARGUMENT**

Alnylam's request to amend its complaint is timely, is not prejudicial to Moderna, is not futile, and promotes efficiency and judicial economy. This motion is filed in accordance with the Scheduling Order's February 15 deadline for seeking leave to amend the complaint to add patent(s) issued after the Scheduling Conference. Alnylam has steadfastly kept Moderna apprised of the prosecution of its continuation patent applications. Indeed, Moderna has been on notice that additional patents could issue, including the one subject to this motion, since at least June 2022, when the applications became public and Alnylam's Chief Intellectual Property Officer emailed Moderna concerning their publication. Moderna was again informed at the Scheduling Conference of the fact that Alnylam expected additional patents to issue. Presuming Moderna was watching the Patent Office's public

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'933 Patent, the '979 Patent, and the '229 Patent.

website, it would have seen that the final claim sets for the '229 Patent were filed on November 30, 2022, that the Notice of Allowability was mailed on December 22, 2022, and that the Notice of Allowability was entered on the Patent Office docket on January 3, 2023. In January 2023, Alnylam informed Moderna of the specific patent to issue and the specific claims Alnylam intended to assert. On February 8, 2023, the Patent Office issued an Issue Notification, assigning a patent number and stating that the '229 Patent will formally issue on February 28, 2023. On February 9, 2023, Alnylam provided the Issue Notification to Moderna. Accordingly, this amendment comes as no surprise to Moderna.

The '229 Patent is a continuation of, and therefore shares an identical written description with, the earlier Asserted Patents. The Joint Claim Construction Statement is not to be filed until March 1, 2023, the Joint Claim Construction Brief is not to be filed until June 28, 2023, fact discovery closes on November 1, 2023, and trial is set approximately a year later, in November 2024. There is no prejudice to Moderna. To the extent there is any, it results from Moderna's refusal to engage in claim construction exchanges relating to the '229 Patent. Moreover, the amendment would not be futile and would promote efficiency and judicial economy by resolving the patent disputes in one proceeding.

### **III. STATEMENT OF THE FACTS**

Alnylam continues to prosecute continuation patent applications related to the '933 and '979 Patents. It has kept Moderna apprised of the status of such patent applications. For example, Alnylam put Moderna on notice of U.S. Patent Application No. 17/651,029 (the "'029 Application")—the application that resulted in the '229 Patent—on June 23, 2022, after the application had published. (Ex. 4.) The Patent Office issued the Notice of Allowability for that application on January 3, 2023. Alnylam promptly paid the issue fee. The Notice is publicly available on the Patent Office website. Alnylam notified Moderna of the Notice of Allowability and payment of issue fee for the '029 Application on January 23, 2023. (Ex. 5.) Subsequently, on January 31, 2023, Alnylam informed Moderna of the claims it intended to assert and asked Moderna to identify potential claim terms for construction, if any. (Exs. 6-7.) Although Moderna has identified fifteen claim terms for construction of the '933 Patent and '979 Patent, it has to date refused to participate in an exchange of claim terms with respect to the '229 Patent.

On February 8, 2023, the Patent Office mailed an Issue Notification that assigned a patent number—U.S. Patent No. 11,590,229—and indicated that the patent will issue on February 28, 2023. (Ex. 8.) Alnylam immediately informed Moderna and requested again that Moderna provide any new claim terms from the '229 Patent for construction. (Ex. 9.) The parties have met and conferred and



following the meet and confer Alnylam reduced the number of claims it intends to assert against Moderna. Even with that concession, Moderna opposes this motion.

Despite Alnylam's request, to date, Moderna has not identified any terms for construction in the claims Alnylam asserts from the '229 Patent.

#### **IV. ARGUMENT**

Under Rule 15(a)(2) of the Federal Rules of Civil Procedure, “[t]he court should freely give leave [to amend] when justice so requires.” “The Third Circuit has adopted a liberal policy favoring the amendment of pleadings to ensure that claims are decided on the merits rather than on technicalities.” *ICU Med., Inc. v. RyMed Techs., Inc.*, 674 F. Supp. 2d 574, 577 (D. Del. 2009) (citing *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990)). This means that leave to amend should be granted absent a showing of “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the amendment, etc.” *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Alvin v. Suzuki*, 227 F.3d 107, 121-22 (3d Cir. 2000); *Vitaworks IP, LLC v. Glanbia Nutritionals (NA), Inc.*, 2021 WL 5061707, \*1–\*2 (D. Del. Oct. 26, 2021) (same).

As explained more fully below, Alnylam’s requested amendment is timely, is not prejudicial to Moderna, is not futile, and promotes efficiency and judicial economy.

A. Alnylam’s Amendment is Timely and Made in Good Faith

A motion for leave to amend that is “filed within the deadline set forth in the scheduling order for amending pleadings, which generally precludes a finding of undue delay.” *Intellectual Ventures I LLC v. Toshiba Corp.*, 2015 WL 4916789, at \*2 (D. Del. Aug. 17, 2015); *see also The Proctor & Gamble Co. v. McNeil-PPC, Inc.*, 1998 WL 1745118, at \*1 (D. Del. Dec. 7, 1998) (granting patentee’s motion for leave to supplement its complaint to add infringement claims for a new patent that issued after the lawsuit was filed). Similarly, courts have found that a timely filed proposed amendment weighs against a finding of bad faith. *See Trueposition, Inc. v. Allen Telecom, Inc.*, 2002 WL 1558531, at \*2 (D. Del. Jul. 16, 2002). Challenges based on bad faith “focus on the plaintiffs’ motives for not amending their complaint... earlier,” *J.E. Mamiye & Sons, Inc. v. Fid. Bank*, 813 F.2d 610, 614 (3d Cir. 1987) (quoting *Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d Cir.1984)), and typically rely on some showing of a “sinister motive” or “nefarious purpose,” *U.S. ex rel. B&R, Inc. v. Donald Lake Constr.*, 19 F. Supp. 2d 217, 221 n.6 (D. Del. 1998).

At the Initial Scheduling Conference on September 1, 2022, the parties and the Court discussed Alnylam’s intention to assert additional patents, should those

patents issue. Alnylam sought a deadline for amending the pleadings of June 28, 2023. After lengthy discussion and the Court noting its expectation that “counsel will be reasonable” on this issue (Ex. 10, Sept. 13, 2022 Tr. at 42:16), the Court set February 15, 2023, as the date by which Alnylam is required to file a motion to amend to add any newly issued patents. (Ex. 10, Sept. 13, 2022 Tr. at 14:1-16:18, 36:4-42:19.) And the Court adjusted the date for the parties’ exchange of claim construction positions from February 15 to February 17. (*Id.* at 41-42.)

Even before the Scheduling Conference, Alnylam put Moderna on notice of the ’029 Application on June 23, 2022. (Ex. 4.) The prosecution of the ’029 Application, including the claims being sought and ultimately allowed, has been publicly available on the Patent Office website since June 9, 2022. Alnylam provided Moderna with a copy of the Notice of Allowance and pending issuance on January 23, 2023, and further notice of the specific patent claims to be asserted on January 31, 2023. (Exs. 5 and 6.) Alnylam reached out to Moderna seeking to meet and confer regarding the proposed Amended Complaint on February 9, 2023. (Ex. 9.) The parties conducted a meet and confer on February 13, 2023, and Moderna informed Alnylam on February 14, 2023 that it would oppose the motion. In an effort to address Moderna’s concerns, Alnylam informed Moderna that it would assert less patent claims from the ’229 Patent than it originally identified.

Moderna cannot argue that Alnylam unduly delayed alleging infringement of the '229 Patent. Alnylam notified Moderna that the patent would issue, identified the claims Alnylam intends to assert, and is seeking leave in accordance with the Court's schedule. By moving to amend within the deadline set by the Scheduling Order, Alnylam has acted properly and has not unduly delayed this matter. *See Intellectual Ventures I*, 2015 WL 4916789, at \*2; *Cloud Farm Assocs., L.P. v. Volkswagen Grp. of Am., Inc.*, 2012 WL 3069390, \*5–\*6 (D. Del. Jul. 27, 2012); *The Proctor & Gamble Co.*, 1998 WL 1745118, at \*1; *see also Automated Layout Tech., LLC v. Precision Steel Sys., LLC*, 2022 WL 17632836, \*2–\*4 (D. Neb. Dec. 13, 2022) (finding that patentee “acted appropriately in waiting to seek to amend its pleading until the patent was actually issued,” and finding “it would be more efficient for the parties and the Court to handle the related patents and related products in the same case”).

#### B. Moderna Will Not Suffer Undue Prejudice

This motion is filed timely, “therefore, there can be no unfair prejudice to defendant.” *See Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 2012 WL 2365905, at \*2 (D. Del. Jun. 21, 2012). Moreover, no undue prejudice exists where, as here, the parties will have ample time to conduct discovery on the newly-added claims. *See Centerforce Techs., Inc. v. Austin Logistics, Inc.*, 2000 WL 652943, at \*6–\*7 (D. Del. Mar. 10, 2000) (holding that the addition of new patent claims is not prejudicial

where discovery remains open, the added patent is closely related to the patents-in-suit, and both claims involve the same accused product). Undue prejudice does not arise where, as here, the patents are directed to the same technology. *LG Elecs. U.S.A., Inc. v. Whirlpool Corp.*, 2011 WL 4043394, \*2 (D. Del. Sep. 12, 2011).

Moderna has no grounds to claim prejudice. Discovery is not scheduled to conclude until November 1, 2023. The trial in this matter is not scheduled to begin for twenty-one months. Only three pertinent deadlines have passed to date—service of Alnylam’s Infringement Contentions on October 27, 2022, service of Moderna’s Invalidity Contentions on December 13, 2022, and the exchange of terms for construction on January 25, 2023—a possibility inherently considered by the structure of the dates set in the Scheduling Order. (Ex. 10, Sept. 13, 2022 Tr. at 39:2-42:13.) The amended complaint includes an infringement claim chart for the ’229 Patent, which enables Moderna to identify claim terms for construction ahead of the Joint Claim Construction Chart deadline and to prepare its invalidity contentions with respect to the ’229 Patent.

There is no prejudice on claim construction or need to delay it. The specification in the ’229 Patent is the same as in the earlier Asserted Patents, and Alnylam has proactively apprised Moderna of the claims it intends to assert. Alnylam’s Opening Brief on claim construction is not due to be served until March 29, 2023, and Moderna’s Answering Brief is not due until May 3, 2023. The Joint

Claim Construction Brief is not due to be filed until June 28, 2023. Thus, there is more than sufficient time to handle claim construction issues, if any, on the '229 Patent in this proceeding. Indeed, Alnylam invited Moderna to identify claim terms for construction from the '229 Patent—in addition to the fifteen terms already identified for the '933 Patent and '979 Patent—prior to the February 17, 2023 exchange of constructions; to date, Moderna has refused to engage in any claim construction exchanges with respect to the '229 Patent until the Court orders it.<sup>3</sup>

The '229 Patent claims similar subject matter to the Asserted Patents and covers the same infringing products. *See Centerforce*, 2000 WL 652943, at \*6. Alnylam's allegations of infringement of the '229 Patent are based on similar evidence as in the original Complaints. (*See* Exs. 1-3.) Any claim by Moderna that the addition of the '229 Patent will prejudice them by adding complexity and difficulty to this matter is not only unfounded, but unsupported by the law of this court. *See Targus Int'l LLC v. Victorinox Swiss Army, Inc.*, 2021 WL 2291978, at \*3 (D. Del. Jun. 4, 2021) (finding that a party's time and effort in defending against a new claim “does not, in itself, amount to undue prejudice” even where the amendment was untimely and would “increase the cost and complexity of the current

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<sup>3</sup> As explained, the Joint Claim Construction Brief is not due to be filed until June 28, 2023. Accordingly, the parties have ample time to work together to ensure claim terms from the '229 Patent, if any, are before the Court by that time.

litigation”). Under the circumstances here where there is complete identity in the patent specifications and accused products, complexity is not a valid ground to deny amendment of the Complaint at this early stage. *Id.*

C. The Proposed Amendment is Not Futile and Promotes Efficiency

A motion for leave to amend is not futile unless it is clear that the amended complaint “would not survive a motion to dismiss for failure to state a claim upon which relief could be granted.” *Alvin*, 227 F.3d at 121; *see also Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 736-37 (D. Del. Mar. 6, 2002). Even then, courts have stated that the “better course is to liberally allow amendments that state a colorable claim and defer judgment as to whether they survive a motion to dismiss for failure to state a claim until such time when that motion is raised.” *Agere Sys.*, 190 F. Supp. 2d at 736. Furthermore, to require “the filing of another lawsuit [covering the same subject matter and Accused Products] would not promote the interests of judicial efficiency.” *LG Elecs. U.S.A.*, 2011 WL 4043394, at \*2.

Just as Alnylam’s original complaints state plausible causes of action, so too does Alnylam’s proposed Amended Complaint. Alnylam’s allegations regarding infringement of the ’229 Patent are similar to those regarding infringement of the current Asserted Patents and are based on virtually the same evidence presented in the original Complaints. (*See* Exs. 1-3(Original vs. Amended Complaint).)

While Moderna has filed a motion to dismiss the original complaints, that motion on its face was “partial,” and even if granted would not resolve all of Alnylam’s claims. *See* (D.I. 12.) Moreover, on the merits, Moderna’s Partial Motion to Dismiss lacks factual and legal support. Tellingly, a similar motion filed in another case before this Court was denied. *See* (D.I. 45-1.) Moderna’s reasoning there—that, under 28 U.S.C. § 1498(a), any infringement claims relating to a Government contract must be litigated exclusively in the Court of Federal Claims—is identical to its position taken in this case. Similarly, Moderna has failed to meet its Rule 12(b)(6) burden here. (D.I. 45-1 at 6-16.) Thus, the amendment is not futile on this basis.

Alnylam’s proposed Amended Complaint seeks to avoid burdening the court with a separate lawsuit alleging infringement of a patent covering similar technology by the same Accused Products at issue in this case. Granting Alnylam’s motion to amend its complaint would only serve to promote the interests of judicial efficiency. *See LG Elecs. U.S.A.*, 2011 WL 4043394, at \*2.

D. Alnylam Does Not Seek to Amend the Scheduling Order and Has, in any Event, Shown Good Cause for the Amendment

In the meet and confer, Moderna’s counsel suggested that Alnylam has failed to show good cause for amending its complaint as required by Rule 16(b)(4). But Alnylam does not seek to modify the Scheduling Order. To the contrary, Alnylam is



adhering to the Scheduling Order. Paragraph 8 of the Scheduling Order (D.I. 28) provides that “All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before February 15, 2023. After this date, no patent related to U.S. Patent No. 11,246,933 or U.S. Patent No. 11,382,979 (a ‘Related Patent’) may be added to this litigation.” As explained herein, Alnylam has timely brought this motion to amend the Complaint by the February 15, 2023 deadline.

Moreover, even if this Court were to address this motion under Rule 16, Alnylam certainly has good cause for this amendment. “In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party.” *Dickerson v. KeyPoint Gov’t Sols., Inc.*, 2017 WL 2457457, at \*3 (D. Del. Jun. 7, 2017) (quoting *ICU Med.*, 674 F. Supp. 2d at 577-78). “‘Good cause’ exists when the Schedule cannot reasonably be met despite the diligence of the party seeking the extension.” *ICU Med.*, 674 F. Supp. 2d at 577 (citing Fed. R. Civ. P. 16(b)(4) Advisory Committee Notes (1983 amendments)). Alnylam has worked diligently to meet the scheduled deadline to amend the complaint and to ensure no other dates need to be adjusted. Alnylam has also worked diligently within the Patent Office procedures to prosecute the ’229 Patent as expeditiously as possible, including requesting prioritized examination under the

Patent Office's Track One program.<sup>4</sup> During this expedited prosecution, Alnylam filed all papers ahead of their deadlines and did not seek any extensions. The '229 Patent will issue on February 28, 2023. Thus, Alnylam has acted diligently and could not have brought this motion any sooner.

## **V. CONCLUSION**

For the foregoing reasons, Alnylam requests that the Court grant this motion for leave to file its First Amended Complaint, attached as Exhibit 1.<sup>5</sup>

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<sup>4</sup> Under Track One, the Patent Office endeavors to provide a final disposition within twelve months of prioritized status being granted. A patentee cannot seek any extension of time to respond and maintain Track One status.

<sup>5</sup> Pursuant to Local Rule 15.1, Alnylam submits with this motion the proposed Amended Complaint and accompanying exhibits with the exception of a copy of the '229 Patent, which will issue on February 28, 2023.

Respectfully submitted,

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Dated: February 15, 2023

**RULE 7.1.1 CERTIFICATE**

I hereby certify that the subject of the foregoing motion has been discussed with counsel for the defendants and that we have not been able to reach agreement.

*/s/ Ethan H. Townsend*

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Ethan H. Townsend (#5813)

**WORD COUNT CERTIFICATION**

The undersigned counsel hereby certifies that the foregoing document contains 3,290 words, which were counted by using the word count feature in Microsoft Word, in 14-point Times New Roman font. The word count includes only the body of the motion. The word count does not include the cover page, tables of contents and authorities, or the counsel blocks.

/s/ *Ethan H. Townsend*

Ethan H. Townsend (#5813)